PMD15

SOCIETAL COSTS OF ROUTINE FOLLOW-UP SERVICES FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES IN GERMANY AND THE UNITED KINGDOM - AND THE IMPACT OF REMOTE MONITORING

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OBJECTIVES: Expert consensus recommends calendar based in-office follow-up (FU) for pacemakers (PM) twice annually, for internal cardioverter defibrillator (ICD) or cardiac resynchronisation therapy devices (CRT) four times a year. To estimate the societal costs of these FUs in Germany and the UK (UK). To estimate potential cost savings from switching from conventional to a BIOTRONIK Home Monitoring FU (remote monitoring) regimen. **METHODS:** Prevalence-based estimates on the number of in-office FU visits were combined with data on private and ambulance transport and hospital services, with costs projected until 2015. **RESULTS:** Annual cost of routine FU in Germany are estimated to climb from EURO 106 mio (2010) to 142 mio (2015). For the UK, costs are forecast to rapidly increase from EURO 31 mio (2010) to 49 mio (2015). In Germany, patients bear the majority of the costs (61%), followed by hospital service costs (31%). In the UK, the situation is reversed with hospital costs contributing the most (84%), followed by patient travel costs (12%). The remainder is health insurance costs for ambulance transport. If 50% of all patients would attend one in-office visit annually and have their other FUs performed with Home Monitoring, annual cost savings in 2015 could reach EURO 43.9 mio in Germany, and EURO 14.7 mio in the UK. **CONCLUSIONS:** For the first time, costs of FU for PM and ICD/CRT in Germany and the UK are presented. As modern devices are capable to self-declare parameter deviations indicative for malfunctions or worsening disease, remote monitoring can help eliminating unnecessary visits. The presented savings are expected to be heavily underestimated due to not considering the impact of earlier event detection and improved disease outcomes. Savings could be invested in remote monitoring technologies, and freed medical specialist capacities be re-directed to CIED patients in real need of FU visits.

PMD16

THE ECONOMIC AND EFFICIENCY GAINS ASSOCIATED WITH THE USE OF A STANDARDISED, AUTOMATED BCR-ABL MONITORING TEST (SBAT): RESULTS FROM A BUDGET IMPACT ANALYSIS FOR THE USA

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OBJECTIVES: In the US the monitoring of patients with Chronic Myeloid Leukaemia (CML) presents extensive intra- and inter-lab variability, thus a standardised, automated test should allow for improvement in patient management and health outcomes. The aim of the study was to estimate the budget impact and improved testing accuracy associated with a the use of a standardised, automated BCR-ABL monitoring test (SBAT) when compared to laboratory developed tests (LDTs) for newly diagnosed CML patients over a 5-year period in the US. **METHODS:** Epidemiology data regarding the incidence of Philadelphia positive (Ph+) CML patients who would be treated with a tyrosine kinase inhibitor (TKI) were combined with workflow cost and accuracy (sensitivity and specificity) data associated with the sequential testing and monitoring of newly diagnosed CML patients. A survey of US laboratories was conducted to determine the labour and materials costs associated with the SBAT versus LDTs. A testing algorithm based on NCCN guidelines was used to capture a number of different tests including testing for major molecular response (SBAT versus LDTs), complete cytogenetic response (routine and FISH-fluorescence in situ hybridisation), and mutation analysis. **RESULTS:** Results indicate that the SBAT is both less resource- and labour- intensive, and can be carried out at a cost that is lower than when an LDT is used. In addition, overall test accuracy increases when the SBAT is used instead of an LDT. For example, for every 100 patients who follow BCR-ABL monitoring according to NCCN guidelines, savings of approximately $386,180 and approximately 327 more accurate test results could be achieved over 5 years. **CONCLUSIONS:** The benefits from a SBAT when compared to LDTs are not only from the reduction of intra- and inter-lab variability (increased accuracy) but also in economic terms due to lower overall costs. Therefore, a SBAT represents a cost-saving alternative versus LDTs.

PMD17

NOBLE METAL ALLOY-COATED URETHRAL CATHETER: A BUDGET IMPACT ANALYSIS IN THE VENETO REGION OF ITALY

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OBJECTIVES: The aim of this paper is to illustrate a methodology to develop a BIA, assisting the decision maker in answering the question on financial sustainability. **METHODS:** The analysis compared the new coated urethral catheter (alternative A) to the long-term catheter currently in use in the region (alternative B). The study, built on efficacy data including "asymptomatic bacteriuria" solely, adopted the perspective of the Regional Health Service. A survey was conducted in seven local health authorities (LHAs) within the Region to obtain consumption data and the average price of respectively the new and currently used long-term catheters. The estimate of regional consumption of alternative B was obtained by projecting the consumption of 7 LHAs on the basis of the percentage of total inpatient admissions. The analysis included technology costs and the costs of additional hospitalization days due to Catheter Associated Urinary Tract Infections (CAUTI). Sensitivity analyses were conducted to test the robustness of the results in the "base case". **RESULTS:** In 2010 approximately 25.000 long-term catheters with an average price of 3.57 € were consumed. The regional estimate of annual consumption is about 221.560 catheters, with a total cost of € 791.000 per year. In the case of adopting alternative A, the base case analysis estimated savings of around € 200.000 per year. The one-way sensitivity analysis confirmed the extreme variability of the final result as a function of the confidence interval of the clinical efficacy. A more favorable result for the new catheter can be reached using a "two-way" analysis, combining a higher CAUTI incidence and a higher level of effectiveness (€2.045.866). **CONCLUSIONS:** The results are strongly influenced by the effectiveness of the new technology: a slight clinical benefit is enough to make the new catheter economically viable.

PMD18

MAST (MINIMAL ACCESS SPINAL TECHNOLOGIES) VERSUS OPEN SURGERY: ACTIVITY-BASED COST ANALYSIS OF SPINAL FUSION PROCEDURE FROM HOSPITAL PERSPECTIVE

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OBJECTIVES: Open spine surgery (OS) is associated with significant muscle trauma leading to delayed recovery, prolonged pain, and significant medical resource utilization. Minimal Access Spinal Technologies (MAST™) aim at minimizing muscle trauma, reduce blood loss, decrease postoperative pain, reduce length of stay in hospital (LoS), and expedite return to normal activities for the patient. The objective of this study is to determine and compare the resource consumption associated with open vs. minimal invasive surgery in patients with degenerative spinal disorder. **METHODS:** This activity-based cost-analysis was conducted in two Italian hospitals where patient flow and resource utilization were mapped and segmented through interviews with medical staff. Unit costs were retrieved from public sources and hospital data for the following categories 1) staff time; 2) tests; 3) drugs/consumables; 4) operating room (OR); 5) spinal implants/instrumentation; and 6) general costs. Costs were compared between pathways (open vs. MAST™) and for each phase (pre-hospitalization, hospitalization, surgery, post-surgery and follow-up. **RESULTS:** Both surgery and post-surgery were the most resource intense episodes: on average post-surgery accounted for 14% of the total costs in MAST™, and 24% in OS. MAST™ was associated with less overall resource use in both hospitals, mainly driven by shorter LoS post surgery (2 vs. 4 days), less blood loss and less demanding wound care. Total hospitalization costs were €6970-8310 for MAST™ and €8021- 8760 for OS. **CONCLUSIONS:** The study confirms published evidence on the shorter LoS with MAST™ and the economic benefits of a less invasive procedure. Despite initial higher investments (instrumentation, learning curve) MAST™ may be an effective and cost-saving alternative to OS. Further cost savings may be incurred due to faster return to work, not investigated in this study.

PMD19

COST-EFFECTIVENESS OF IMPLANTABLE DEFIBRILLATORS AFTER MYOCARDIAL INFARCTION BASED ON 8-YEAR FOLLOW-UP DATA (MADIT II)

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OBJECTIVES: About 190,000 Germans suffer a myocardial infarction (MI) each year. Of these, 25% may be eligible for an implantable cardioverter defibrillator (ICD) due to low left ventricular ejection fraction. Given the high costs of implantation, the purpose of this study was to assess the cost-effectiveness of ICDs compared to conventional therapy in patients with an ejection fraction ≤ 30% after MI in Germany. **METHODS:** The economic evaluation was performed from the perspective of the German statutory health insurance (SHI). In order to simulate costs and effectiveness over lifetime, a Markov model was constructed with 7 health states. The model was based on 8-year follow-up data for ICD implantation after MI (MADIT II), which were published recently. **RESULTS:** The analysis shows that ICD implantation compared to conventional therapy in patients fulfilling MADIT-II criteria has a cost-effectiveness ratio of €44 736 per quality-adjusted life year gained. If every patient insured by the SHI and fulfilling the MADIT-II criteria would receive an ICD, the model suggests expenditures between €173 million and €1.7 billion per year. **CONCLUSIONS:** ICD therapy cannot be considered clearly cost-effective when compared to many well-accepted interventions. If policy makers decide to reimburse ICDs in the MADIT-II population, they will need to either raise premiums or abandon coverage for other currently funded medical interventions.

PMD20

COST ANALYSIS OF RECHARGEABLE DEEP BRAIN STIMULATOR IN DYSTONIA

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OBJECTIVES: Deep brain stimulation (DBS) use in dystonia is associated with high energy needs and as such frequent replacement of the device. The first rechargeable DBS device (Activa®RC) offers a guaranteed 9 years longevity. Our objective is to perform a cost analysis of Activa®RC compared to the non rechargeable neurostimulators in dystonia patients in France. **METHODS:** A retrospective data collection was performed in a Neurosurgery Department (Pr. Ph. Coubes - Montpellier Public Hospital) with significant experience in DBS for dystonia. The cost analysis was based on direct medical costs, from a national insurance perspective. The evaluation concerns the device and hospitalization tariffs, the procedure cost being included in the hospitalization tariffs, in France, for the public hospitals. We compared the time to replacement with non-rechargeable devices versus rechargeable device, extrapolated over 9 years. A sensitivity analysis was performed using time-to-replacement variable. **RESULTS:** The cohort included 63 consecutive dystonia

patients, implanted with a non-rechargeable device (Kinetra™, Soletra™, Itrel®2) between 1996 and 2010. Overall, 117 implantations were performed (primo-implantation and replacement). The mediane time to replacement of the non-rechargeable devices was 2.9 years, ranging between 0.4 and 7.8 years. When extrapolated to the cohort population, the use of the rechargeable device would have avoided a total number of 215 hospitalizations over 9 years. The number of days of hospitalization avoided per patient was 10 days. The direct medical cost (device and hospitalization tariffs) avoided per patient was 27 886€. **CONCLUSIONS:** Over 9 years, the rechargeable DBS device allows to avoid 2 device replacements per patient. This is associated with a 40 % reduction of the total number of days in hospital, and 43% reduction in the direct medical cost. The rechargeable neurostimulator Activa®RC is adapted to patients with high energy needs like dystonia patients, with a time to replacement of 5 years or less.

PMD21

THE CLINICAL AND ECONOMIC BENEFITS OF SPINAL CORD STIMULATION IN THE TREATMENT OF FAILED BACK SURGERY SYNDROME (PRECISE STUDY)

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OBJECTIVES: PRECISE study aims to assess the costs and the clinical benefits of Spinal Cord Stimulation (SCS) (plus conventional medical management, CMM) in the treatment of Failed Back Surgery Syndrome (FBSS) patients not adequately responding to CMM alone. Being the study closed, we report the preliminary clinical and resource consumption final results. **METHODS:** An observational, pre-post data collection with a 24-months follow-up (FU) was developed in 9 Italian Hospitals. Resource consumption, clinical outcomes (Pain Numerical Rating Scale - NRS, Oswestry Disability Index - ODI) and HR-QoL data (SF-36, EQ-5D) were collected before and after the SCS system implantation in order to be compared. **RESULTS:** Fifty-five of the 72 patients implanted (out of the 80 enrolled for the SCS screening) completed the study. Seventeen discontinued the therapy due to: consent withdrawal (24%), loss to FU (24%), SCS-related issues (29%), non-SCS related reasons (24%). Mean pain intensity decreased from 7.4±1.4 to 4.2±2.6 in the first 12 months, remaining consistent through the second year of FU (4.1±2.5). A continuous improvement in function measured with ODI was appreciated: 47 (85%) patients improved in the first year and 33 (60%) during the second, for a total of 41 (82%) patients improved at 24-month FU if compared to the baseline. EQ-VAS increased from 37 to 60 (12-months) to 63 (24-months). All SF-36 domains significantly improved, and especially "Bodily Pain", "Social Functioning", "Role Emotional". With respect to the baseline, the monthly per-patient resource consumption decreased: considering the second year of follow-up, both pain-related hospitalizations and GP visits experienced a 70% reduction in number, diagnostic exams diminished by the 82%. Monthly caregivers' days off from work dropped by the 80% (from 45 to 9). **CONCLUSIONS:** SCS allows a better and sustained pain control and HR-QoL improvement. If compared with CMM alone, SCS permits a reduction in resource consumption and productivity losses.

PMD22

ECONOMIC EVALUATION OF AMINO-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) TEST IN PATIENTS WITH DYSPNEA ATTENDING TO EMERGENCY DEPARTMENT (ED) IN SPAIN

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OBJECTIVES: Diagnosis of patients with dyspnea and suspected acute heart failure (HF) using NT-proBNP testing has been studied internationally. We aimed to analyze the efficiency of NT-proBNP compared to standard clinical evaluation alone use in Spanish Emergency Departments. **METHODS:** A decision-analytic model was developed to evaluate the clinical and economic outcomes of both diagnostic alternatives. Model's time horizon started at patient ED visits and ended after 60 days of follow-up (taking into account differences between hospitalized and non-hospitalized patients). Clinical parameters were mainly extracted from the PRIDE study and were validated by expert opinion (ED and cardiology doctors). We assumed that 65% of patients with dyspnea had HF based on Spanish published data. Resource use was obtained through expert opinion and examined under a National Healthcare System (NHS) perspective. We considered a 900 pg/ml cut-point for NT-proBNP test (sensitivity of 90% and specificity of 85%). Our model compared final diagnostic result with the initial diagnostic before ED discharge. A probabilistic sensitivity analysis was carried out in order to handle uncertainty. **RESULTS:** Diagnosis using NT-proBNP testing was correct in 91.96% of patients (59.09% true positive cases and 32.87% true negative cases) versus 85.53% with the standard clinical evaluation alone (50.79% of true positive cases and 34.74% of true negative cases). Besides, NT-proBNP testing involved less costs (4,045€ versus 5,405€) mainly due to less hospitalizations and a shorter length of stay. Robustness of results was confirmed through a sensitivity analysis. **CONCLUSIONS:** NT-proBNP test is less costly per correctly diagnosed patient than standard clinical evaluation alone in the assessment and management of patients with dyspnea at ED rooms from Spanish NHS perspective.

PMD23

CHARACTERIZATION OF FOCAL LIVER LESIONS BY CONTRAST-ENHANCED ULTRASOUND IN THE NETHERLANDS: AN ECONOMIC EVALUATION

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OBJECTIVES: Liver imaging techniques aim to correctly characterize focal lesions and influence choices of therapeutic strategies. The objective of this study was to compare diagnostic efficacy and direct medical costs of contrast-enhanced ultrasound (CEUS) to magnetic resonance imaging (MRI) or computed tomography (CT) in the characterization of focal liver lesions in the The Netherlands. **METHODS:** This prospective study enrolled 170 patients at an academic hospital in the The Netherlands. A decision model was designed to compare two diagnostic algorithms based on the results of the study: 1) a typical patient work-up, which included ultrasound (US), followed by an MRI or CT examination, and 2) a new patient work-up in which CEUS was performed after US. The perspective of the healthcare sector in the The Netherlands was used. Clinical outcomes were 'correctly characterizedx benign and malignant liver lesions and life-years (LY). Model inputs were taken from the hospital database, literature and publicly available sources. Time horizon was two years. One-way and probabilistic sensitivity analyses were performed to assess uncertainty in the results. **RESULTS:** CEUS was able to identify benign and malignant focal liver lesions with a sensitivity of 96.9% and specificity of 92.3%. For correct tumor subgroup characterization, sensitivity and specificity were 86.2% and 85.6% respectively. Base-case results revealed that the CEUS strategy had similar effectiveness compared to the MRI/CT strategy (incremental effects of 0.002 LYs) and resulted in cost-savings of €452. The cost-savings for diagnostic phase and treatment phase were €160 and €292 respectively. The results were sensitive to specificity, sensitivity and cost of the diagnostic tests. Robustness of the results was confirmed by probabilistic sensitivity analysis. **CONCLUSIONS:** This study demonstrates that CEUS is a cost-saving alternative compared to the traditional diagnostic procedures and should be considered as one of the 'first stepx options in the front-line characterization of focal liver lesions in the The Netherlands.

PMD24

COST-EFFETIVENESS OF 3M ™ COBAN 2 ™ COMPRESSION SYSTEM IN THE TREATMENT OF LYMPHOEDEMA

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OBJECTIVES: The treatment of chronic lymphoedema (CL) is of particular health economic interest since, due to its chronic nature and continuous need for treatment, it is associated with high costs and considerable patient burden. The objective of this study was to assess the cost-effectiveness of 3M™ Coban 2™ compression system in the treatment of CL compared to Comprilan® short-stretch bandage compression therapy. **METHODS:** In the UK and the United States a multi-center, prospective, open-label study was conducted, including patients with CL of the legs (n=40) and the arms (n=42). Patients were randomly assigned to the four treatment arms (3M™ Coban 2™ compression treatment either daily, 2x/wk or 3x/wk, and daily compression therapy with Comprilan® bandages). Cost analysis from the UK payors' perspective was based on material costs and personal resource utilization for bandage changes and for manual lymphtherapy. Clinical outcomes in the cost-effectiveness analysis was defined as mean volume reduction at the end of therapy (19 days). **RESULTS:** On average, 3 weeks treatment for a patient with lymphoedema added to 1,297.96 € for the health service comissioners and up to 576,54 € for the physiotherapists across all groups. Lymphoedema treatment with 3M™ Coban 2™ compression system twice a week was more cost-effective than the other treatments (ICER 37.65 € per % reduction of circumference vs. 146.60 € (daily), 145.67 € (3x/wk) and 147.53 € (daily compression therapy with Comprilan® bandages)). Results were comparable for patients with CL of the upper and lower extremities, respecitvely. Sensitivity analysis provided stable results after variation of costs, utilization rates and clinical outcomes. **CONCLUSIONS:** Treatment of lymphoedema with 3M™ Coban 2™ compression system twice a week is more efficient than treatments applied daily or three times per week.

PMD25

COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) IN HIGH-RISK OR INOPERABLE PATIENTS WITH SYMPTOMATIC AORTIC VALVE STENOSIS IN SPAIN

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OBJECTIVES: Transcatheter aortic valve implantation (TAVI) represents an innovative technology superior to medical management (PARTNER study, US) in inoperable patients with severe aortic valve stenosis (AVS). This study aims to estimate the cost-effectiveness of TAVI compared to conservative medical management in symptomatic AVS patients in Spain. **METHODS:** A economic longitudinal cohort model was used to predict clinical and economic outcomes of symptomatic AVS patients treated with either transapical (TA) or transfemoral (TF) TAVI, or medical management alone (MEDICAL). Clinical model input data for TAVI was derived from the real-world SOURCE registry, and for MEDICAL from literature and a registry of 60 untreated Spanish AVS patients followed up for 336 days. Health utilities as well as resource use and unit costs utilized for modelling are representative for Spain. Missing information was substituted by expert estimates. Economic results